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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,147	07/09/2001	Nicholas B. La Thangue	620-149	4292

23117 7590 02/23/2004

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,147	LA THANGUE ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-37* is/are pending in the application.

4a) Of the above claim(s) *33-35 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27,30-32 and 36* is/are rejected.

7)☒ Claim(s) *28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence alignment*.

DETAILED ACTION

Election/Restrictions

Applicant's amendment filed on 11/18/2003 is acknowledged. All previously examined claims are cancelled and new claims 21-37 are presented. Claims 21-32, 36 are deemed to correspond to the previously examined invention.

Claims 33-35 and 37 drawn to method remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) for reasons in the Office action mailed on 6/18/2003.

This application contains claims 33-35, and 37 drawn to an invention nonelected with traverse in the Response filed on 3/31/2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 21-37 are pending and claims 21-32, and 36 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejections.

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 11/18/2003 has been considered. The substance of the changes in Fig. 1 is acceptable to the Examiner, and the changes would obviate the objection of record to the specification. The substance of the changes in Fig. 3 is not acceptable to

the Examiner because the drawing introduces new symbols H2* and H4* that were not present in the specification originally filed.

Both proposed drawing corrections of Fig. 1 and Fig. 3 do not meet the formal requirements for a proposed drawing correction, because it was not filed as a separate paper and because it was not in the form of a pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted. See MPEP § 608.02(v).

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities -- 37 CFR 1.85**

   New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

   All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

3. **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Sequence Rules, Maintained

The objection of the specification is still being maintained because the proposed drawing correction of Fig. 1 is not acceptable for the formal matter as discussed above.

The disclosure remains objected to for reason of record because the specification does not describe the peptides being used in the X-axis of the instant Fig. 3. The disclosure at pages 29-30 appears to say that the peptides listed as H-H7 at Fig. 1 are same as the peptides used at Fig. 3 but the label in Fig. 1 and Fig. 3 have different symbols, which causes confusion. The proposed drawing correction of Fig. 3 is not acceptable because the proposed figure introduces new symbols as explained above

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Applied to New claims

The rejection of claims 10 and 11 (now canceled) under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is now applied to claims 30, and 31. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a pharmaceutical comprising the various peptides. As stated in the prior Office action, this rejection is based on the specification at page 19,

where it asserts that the claimed peptides claimed could be used in treatment of cancer or psoriasis.

Applicant argues: the parent case, now US Pat. 6,268,334, which contains the same disclosure as the present application, was found to enable claims to a polypeptide of the present invention in a "pharmaceutically acceptable carrier"; claim 1 of US Pat. 6,268,334 include a pharmaceutical which the Patent Office has recognized is supported by an enabling disclosure; the applicants assume that present Examiner is not now asserting a position contrary to a prior Patent Office determination with regard to patentability. These arguments and comments have been fully considered but found unpersuasive for following reasons.

The Office notes that claim 1 of US Pat. 6,268,334 recites "pharmaceutically acceptable carrier. However, "pharmaceutically acceptable carrier" is different from pharmaceutical as the instant specification at page 12 lines 19-30 teaches. The specification teaches that the claimed peptide is the pharmaceutical and pharmaceutically acceptable carrier is an inactive ("accessory" line 30 of page 12) ingredient such as solvents ("liquid" line 31 of page 12) suitable for in vivo administration. Claim 1 of the patent says "A surgical stent which comprises a coating incorporating a polypeptide in a pharmaceutically acceptable carrier, the polypeptide consisting of the amino acid sequence of SEQ ID NO: 3, or a variant thereof having from 1 to 5 amino acid substitutions, the variant retaining the ability to antagonize the formation of a DP/E2F." It appears that claim 1 of the patent is drawn to a medical device coated with a peptide consisting of SEQ ID NO:3 or its variants, wherein said

peptide or said variant is dissolved in pharmaceutically acceptable carrier such as saline. Claim 1 of the patent is not drawn to pharmaceutical comprising instantly claimed peptides as an active ingredient.

Applicant argues Example E demonstrate the instantly claimed peptide activate a cell's apoptotic program; Example F of the present application demonstrate that claimed peptide in combination with ecoposide has the highest antiproliferative effect; the Office cited references have limited relevance. These arguments have also been fully considered but found unpersuasive because the specification does not demonstrate any in vivo model data or its equivalent demonstrating that instantly claimed pharmaceutical could be used in vivo for treating a disease without undue experimentation. As stated in the previous Office action, cancer therapy art is unpredictable as the previously cited numerous references demonstrate. The art recognizes that treating cancer and/or psoriasis is not a trivial matter. Considering the state of art, limited guidance in the specification, in the absence of a working example or other evidence of the claimed pharmaceutical's effectiveness, it is maintained that undue experimentation would be required to practice the invention as claimed.

Claim Rejections - 35 USC § 102, Applied to the Newly Presented Claims

The rejection of now cancelled claims under 35 U.S.C. 102(e) as being anticipated by US Pat 5,863,757 (filing date of May 11, 1995) is applied to claims 21-24, 32, and 36.

The claims are interpreted as drawn to a polypeptide consisting essentially of SEQ ID NO:1, and composition comprising said polypeptide and an art-known

pharmaceutically acceptable carrier (claim 32) or a cytostatic or cytotoxic agent (claim 36).

The Office regrets that applicant did not receive the sequence alignment as indicated in the front page of the Office action. A copy is attached with this Office action. As stated in the Office action, instantly claims read on many of the protein sequences for example, Fig. 10 and SEQ ID NO:11 of US Pat 5,863,757. Further, the patent teaches at column 6 teach various formulation suitable for oral, topical, parenteral administration. For new claim 36, the instant specification at page 15, 2nd paragraph says that immunomodulatory compound is a cytotoxic or cytostatic agent. Therefore the various antibodies and fragments at column 6 of the patent are considered as cytotoxic or cytostatic agent.

Applicant argues that "consisting essentially" of SEQ ID NO:1 means at most 47 amino acid in length. The peptide (72 amino acids) of the art is longer than the instantly claimed invention. This argument is fully considered but found unpersuasive for following reasons.

The following is the direct quotation from the specification at page 6, lines 19-27.

> By "consisting essentially" it is meant that the sequence is not, to any significant degree, part of a larger peptide sequence, e.g. the DP-I polypeptide. This is not however to exclude entirely the presence of a small number, e.g. from 1 to 5 amino acid residues at the N- or C- terminus where the presence of such residues have no significant effect on the function of the polypeptide.

This definition of "consisting essentially" in the specification as originally filed is different from what applicant now argues. The specification as originally filed says one example ("e.g.") of the claimed peptide has 1 to 5 amino acid at either and/or both ends.

However, the specification as originally filed does not reasonably convey that 72 amino acids peptide consisting essentially of instant SEQ ID NO:1 is outside of instantly claimed invention. In summary, applicant argument traversing the rejection of record is considered as arguing with meaning of "consisting essentially" not present in the specification originally filed.

The rejection of now canceled claims under 35 U.S.C. 102(e) as being anticipated by US Pat 5,859,199 (filing date of May 15, 1996) is applied to claim 25.

The claim is interpreted as drawn to a variant of SEQ ID NO:1 with 1-5 amino acids difference from SEQ ID NO:1.

The claimed invention reads on SEQ ID NO:4 of US Pat 5,859,199 (a copy of sequence alignment attached again) because the art sequence is one amino acid different at position 163 of DP-1 (i.e. Lys to Glutamic acid change) and smaller than DP-1. See interpretation of "consisting essentially" above.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is confusing. First, it is not clear whether "the consisting essentially of" to "A polypeptide fragment" or "the polypeptide". Second, Does "the polypeptide" refer

to "A polypeptide"? What is the relationship between "A polypeptide fragment" in line 1 and "fragment" in line 4? This rejection affects the dependent claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

LARRY R. HELMS, PH.D
PRIMARY EXAMINER